PUBLIC NOTICE
FINDING OF NO SIGNIFICANT IMPACT

Pursuant to the regulations implementing the provisions of the National Environmental Policy Act (NEPA), the Joint Vaccine Acquisition Program (JVAP) gives notice that an environmental assessment (EA) has been prepared for proposed JVAP activities at Greer Laboratories, Inc in Lenoir, NC.

The proposed action involves JVAP-sponsored work on vaccines based on viral, bacterial, or toxin materials requiring biological safety procedures up to Biocontainment Level 3 (BL-3) at Greer Laboratories, Inc. The EA describes and analyzes the potential adverse environmental impacts associated with these proposed activities. Proposed JVAP-sponsored activities at Greer Laboratories will be consistent with the capabilities and experience already existing at Greer Laboratories.

The first of the proposed JVAP-sponsored activities at Greer Laboratories involves the production of biological defense recombinant DNA vaccine for equine encephalitis. Manufacture of the vaccine will be conducted by growth of an attenuated vaccine strain in cell cultures. The attenuated vaccine strain was produced by recombinant DNA technology to provide the means to produce a safe and effective vaccine. The attenuated virus to be used is not pathogenic in animal models tested to date.

Alternatives considered include (a) performing JVAP activities at another location, (b) producing the vaccine by an alternate method, and (c) not performing JVAP activities. These alternatives were determined to be infeasible or less favorable than the proposed action.

Potentials for direct adverse environmental effects evaluated in the EA include air quality, noise, odor, water quality, solid waste disposal, human health and safety, and utilities. Potential indirect effects evaluated included socioeconomic effects, impact due to renovations, and aesthetics. Additional analyses required under NEPA that were addressed include determination of land use conflicts, unavoidable adverse environmental effects, and cumulative impact. The EA concludes that no significant adverse impact on human health or the environment is anticipated from proposed action. The potential for adverse impacts of the various operations on the laboratory workers would be minimized by a combination of adherence to strict safety procedures and approved standard operating procedures (SOPs), handling of biological materials in biosafety cabinets, and use of personal protective equipment. No effects on cultural or historic resources and no land use conflicts are expected, since an existing building at Greer Laboratories will be used for the proposed action.

A notice of availability of the EA was published in the North Carolina Environmental Bulletin on September 12, 2000 with a 30-day comment period. No comments were received during this time; hence the finding of no significant impact is hereby finalized. The point of contact for this action is: Joint Vaccine Acquisition Program (JVAP), Program Management Office (PMO), Attention: Jennifer Starks, 1436 Porter St, Fort Detrick, Maryland 21702-5041.

Approved by:

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18 Oct 00
Date

JOINT VACCINE ACQUISITION PROGRAM
PROJECT MANAGEMENT OFFICE

Environmental Assessment
of
Joint Vaccine Acquisition Program-Sponsored Activities
at Greer Laboratories, Inc., Lenoir, North Carolina

Prepared on behalf of the
Joint Acquisition Program Office

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1.0 Purpose and Need for the Proposed Action

Because of the current threat of biological warfare and its continuing proliferation, there is an urgent need to protect U.S. military personnel from biological warfare agents. The primary objective of the Joint Vaccine Acquisition Program (JVAP) is to develop, produce, store, test, and field sufficient quantities of U.S. Food and Drug Administration (FDA) licensed vaccines to implement U.S. government policy for protecting its armed forces against death and disease resulting from biological warfare agents. The DoD implements the JVAP through the Joint Program Office for Biological Defense (JPO BD) with the Army serving as the DoD executive agency. Detailed information about the JVAP program can be found in the programmatic environmental assessment.[1]

As required under the National Environmental Policy Act (42 U.S. Code [USC] 4321-4347), Federal agencies must consider the potential for adverse environmental impacts associated with proposed actions. The Council on Environmental Quality (CEQ), Executive Office of the President, has promulgated regulations implementing NEPA (40 CFR, Parts 1500-1508). Army Regulations (AR) 200-2 (Environmental Effects of Army Action, December 1988) is the Department of Army's implementation of NEPA and CEQ regulations. JVAP-PMO environmental policy and procedures requires compliance with all NEPA-relevant Army, DoD regulations. The program manager of the JVAP is the management lead in ensuring NEPA compliance for JVAP actions.

This environmental assessment (EA) addresses JVAP-sponsored activities involving work with viral, bacterial, or toxin materials requiring biological safety procedures up to Biocontainment Level 3 (BL-3) that are proposed to be conducted at Greer Laboratories, Inc in Lenoir, NC. One of the activities proposed to be conducted at Greer Laboratories involves the production of a biological defense recombinant DNA vaccine for equine encephalitis. The production of equine encephalitis vaccine is needed to assure an adequate supply is available to protect U.S. military personnel who may be exposed to the agent that causes the disease. This EA describes and analyzes the potential adverse environmental impacts associated with the proposed JVAP activities at Greer Laboratories, particularly the equine encephalitis vaccine production.

2.0 Description of the Proposed Action

2.1 Brief Summary of Proposed JVAP Activities at Greer Laboratories

Proposed JVAP-sponsored activities at Greer Laboratories will be consistent with the capabilities and experience already existing at Greer Laboratories. Such activities may require varying levels of biocontainment up to BL-3. The main focus of this EA is the production of a recombinant DNA equine encephalitis vaccine. This activity is typical of the JVAP sponsored actions that will be conducted at Greer Laboratories. Manufacture of equine encephalitis vaccine will be conducted by growth of an attenuated vaccine strain in bacterial cell cultures. The attenuated vaccine strain was produced by recombinant DNA technology as a way to produce a safe but effective vaccine. An attenuated virus is a weakened virus with reduced ability to infect or produce disease.

[1] Joint Vaccine Acquisition Program; Final Programmatic Environmental Assessment, August 1997

Attenuated viruses are often used in vaccines because they produce an effective immune response but pose little risk of infection. Recombinant DNA molecules are molecules that are constructed in a host, normally a bacteria or yeast in culture, by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell. Recombinant technology can be used to produce an organism (a recombinant virus in this case) that is similar to the parent organism but differs in some important way. In this case, the recombinant virus produces essentially the same immune response as the agent that causes equine encephalitis but it poses little risk of infection. No highly virulent stocks will be stored at the facility or used in the production of the equine encephalitis vaccine. The live attenuated recombinant virus to be used is not pathogenic in animal models. Still, the recombinant virus will be handled under the requirements for biosafety level (BSL) 3 as specified by the Centers for Disease Control and Prevention.[2]

Production of the vaccine involves the following processes:

- Production of master cell bank of E.coli (bacteria) that hosts vaccine candidate virus strains for equine encephalitis
- Master virus seed production
- Working virus seed preparation
- Bulk vaccine production under current Good Manufacturing Practices (cGMP).
- Final product formulation and vialing.
- Lot release testing

The specific production process is being developed at the National Cancer Institute Frederick Center Research and Development Center (Frederick, MD). The final process is expected to involve the production of vaccine in small batches of up to 10 liters in volume.

2.2 Organization, Location and Facilities

2.2.1 Overview of Greer Laboratories, Inc. Greer Laboratories, Inc is a ninety-five year old privately held pharmaceutical company located on Nuway Circle in Lenoir, North Carolina. Greer Laboratories has three buildings totaling approximately 85,000 square feet devoted to manufacturing, testing and administration at its main campus. A portion of one building, known as building #6, will be devoted to the JVAP activities.

Greer Laboratories specializes in the development and production of products for allergy testing and treatment. This includes the production of allergen extract. The safety measures, containment procedures, engineering controls, and waste management procedures that will be used for JVAP-sponsored activities are essentially consistent with those required for the other processes routinely carried out at Greer Laboratories. In addition, Greer Laboratories produced vaccine for the Department of Defense from 1993 through 1995. The proposed work in support of JVAP will be very similar to the previous project in terms of processes, biosafety procedures, containment, and waste management. Greer has an existing Registration for Select Agents with the Centers for Disease Control and Prevention for the use of various etiologic agents. This registration is currently under process for modification to include equine encephalitis.

2.2.2 Facilities Dedicated to JVAP Activities. There are two laboratory rooms within building #6 that may be used for JVAP sponsored activities, room 115 and room 123. Figure 1 shows the current configuration of building #6 including these laboratories. The area used for JVAP sponsored activities will be operated under BSL-3, as specified by the Centers for Disease Control and Prevention. The laboratories proposed to be used for JVAP activities are currently

[2] DHHS Publication, Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH), 4th edition, May 1999

equipped with class II, Type A Biological Safety Cabinets (BSCs) which are certified at least biannually. BSCs may be certified more frequently following maintenance or repair. The general ventilation laboratory supply and exhaust air is filtered through high efficiency particulate air (HEPA) filters with an efficiency greater than 99.97% in removing particulates to 0.3 microns in size. Although individual virus particles are smaller than 0.3 microns, the HEPA filters are standard equipment for BSL-3 labs because they have been shown to be effective in filtering virus particles due to the tendency of viruses to clump. The exhaust fans are tied into the emergency power. The delay for the generator is 10 seconds maximum. Room F115 has a recirculated horizontal air flow pattern. Air is supplied through HEPA filtered air wall module. The negative pressure differential is achieved by the air re-circulation system and by a separate HEPA filtered ventilation system that exhausts to the outside. At least 12 to 15 air changes per hour are provided in the laboratory facilities. Room 123 has a separate dedicated air handler unit and exhaust system.

2.2.3 Proposed Modifications to the Existing Facility. The CDC/NIH guidelines include the following requirements for BSL-3 laboratory facilities:

- The lab is separated from areas that are opened to unrestricted traffic flow within the building and access to the lab is restricted. Passage is through a series of two self-closing doors. Doors are lockable.
- Each lab room contains a hands-free sink for handwashing located near the exit.
- The interior surfaces of walls, floors, and ceilings are constructed for easy cleaning. Walls, ceilings, and floors are smooth and impermeable to liquids. Penetrations in floors, walls, and ceilings are sealed. Openings and spaces such as around doors are capable of being sealed.
- All windows in the laboratory are closed and sealed.
- A method for decontaminating laboratory waste is available in the facility (i.e. autoclave)
- BSCs are required and are located away from doors, air supply louvers, and heavily - traveled areas.
- A ducted exhaust air ventilation system is provided which creates negative pressure by drawing air into the lab from "clean" areas and toward "contaminated" areas. Exhaust air is not recirculated to any other area of the building.
- An eyewash station is readily available inside the laboratory.
- Illumination is adequate for all activities.

The existing laboratory rooms 115 and 123 in building already have many of these features. Where necessary, modifications to the facility will be made to assure that the laboratory rooms meet the CDC/NIH standards for BSL-3. The ventilation system will be reassessed and redesigned, as needed, to ensure that a cascading airflow into the BSL-3 area is maintained and the BSL-3 areas are negative in relationship to all other areas. If necessary, a BSC and an autoclave will be installed or relocated. Additional equipment may also be installed if needed to support the JVAP sponsored activities. For example, a lyophilizer (freeze drier) may be needed to prepare the vaccine for packaging. Equipment necessary for packaging/vialing may also be installed.

2.2.4 Staffing. Greer Laboratories, Inc currently employees approximately 230 people. Most are located at the corporate headquarters, in Lenoir, NC. Currently, one professional staff member and three technical employees are designated for JVAP manufacturing activities. If needed, additional personnel may be drawn from other sections within Greer Laboratories to work on the JVAP project.

2.3 Safety Policies and Procedures at Greer Laboratories

2.3.1 General Safety Requirements. It is official company policy to provide and maintain safe and healthful working conditions for all employees. Conversely, safe work practices by all employees are a requirement at Greer Laboratories. It is the responsibility of all supervisors to ensure that their workers have been trained to recognize the potential hazards of the job and to work according to Greer Laboratories safety rules. The rules are prominently posted in each facility. In addition, a written facility safety plan addresses two fundamental areas of concern: 1) workplace health and safety and 2) environmental hygiene. A comprehensive health and safety program is administered at Greer by the Environmental Health and Safety Officer.

2.3.2 Risk Assessment. The Greer Laboratory Office of Health and Safety reviews the potential risks to personnel for all company operations. Health and safety information is obtained and forwarded to supervisors for use in employee training. Work operations are analyzed to identify those with the greatest potential for exposure. Where necessary, job safety analyses and system safety analyses are used to identify and quantify risks.

2.3.3 Occupational Medical Program. Greer Laboratories maintains an active and effective occupational medical program. An essential element of this program is medical surveillance to monitor the health status of all employees for their protection and for the protection of company operations. Early detection and treatment of infectious diseases ensures that employees can successfully complete their work without posing health or safety risks to themselves or others.

2.3.4 Accident Reporting. Employees are required to report all work-related injuries and illnesses within 24 hours of the incident. The individual's supervisor and the Occupational Health and Safety Officer investigate all injuries and illnesses to determine if any corrective action is necessary to prevent a reoccurrence. Information about work-related accidents and illnesses is maintained in a computerized database which facilitates trend analysis.

2.3.5 Inspections. The Office of Health and Safety conducts inspections of all Greer Laboratory facilities on a regular basis. BSL3 areas are inspected monthly. A report of findings is sent to the persons responsible for the facility with recommended corrective actions, if appropriate. When findings are noted, follow-up inspections are conducted to assure corrective actions are taken. Records of the inspections are maintained by the Health and Safety Office.

2.3.6 Emergency Procedures. Each facility within Greer Laboratories has an emergency plan which includes evacuation procedures, decon procedures, and emergency telephone numbers. Employees working in the area are required to review emergency procedures as part of their SOP review. To further facilitate emergency response, all exits are marked and routes of egress are posted in each facility. Emergency telephone numbers for fire, rescue, police, and poison control are posted in the facilities.

Local emergency responders including the Caldwell County Ambulance Service, the Lenoir Police Department, and the Lenoir Fire Department have entered into memorandums of understanding acknowledging their awareness of the JVAP actions at Greer Laboratories and verifying their ability to support an emergency that may result from the proposed action. These emergency responders have been given the facility safety plan, floor plans of the facilities, and lists of hazardous materials in storage. They also had the opportunity to tour the facilities.

2.3.7 Personal Protective Equipment. Although engineering controls constitute the primary means to protect personnel working with hazardous materials, appropriate personal protective equipment is used by workers to afford an extra level of protection. This includes

goggles, mask, gloves, and gown or scrub suit. The Greer Laboratory Office of Health and Safety, in conjunction with the supervisor, determines the necessary personal protective equipment for use by employees.

2.3.8 Training. Biosafety training is given to all newly hired employees and to tenured workers at 12 to 18 month intervals. In addition, on-the-job biosafety training is performed by the work area supervisor during day-to-day operations. All training is documented in employee records. The Office of Health and Safety conducts periodic specialized training sessions on topics such as carcinogen handling, flammable liquid handling, biohazards, etc. Safety information is conveyed to employees through special bulletins. Records are maintained of all training provided to employees for a period of 5 years.

2.3.9 Security. Access to the laboratory is strictly controlled. All exterior doors to building #6 are kept closed and locked. An electronic key card is required to gain access. A second electronic keypad code must be entered to proceed beyond the office area into the laboratory area. Inside the laboratory area, freezers used to store infectious materials are locked with a padlock. Keys and codes are issued to designated staff members only. Inventories of infectious stock are recorded on inventory log forms as stocks are placed in the freezer. Removal of stocks from the inventory requires a written request authorized by the department director. Records are witnessed by two staff members. Building #6 is protected by a 24-hour electronic security system monitored by the Caldwell County Sheriff Department.

2.3.10 Decontamination Procedures. When necessary, floors, countertops, and other surfaces that are resistant to corrosive materials are decontaminated with Roccal®, a commercial quaternary disinfectant-sanitizer. Roccal® is used in accordance with label instructions and is usually wiped on surfaces to be decontaminated. When necessary to disinfect the entire biological suite, formaldehyde fumigation is used. Formaldehyde is a commonly used biological disinfectant. In-house personnel who are trained in appropriate fumigation protocols perform the fumigation. The area to be fumigated is completely sealed to prevent air from leaking into or out of the area. Then paraformaldehyde flakes are heated to produce formaldehyde gas which permeates the area being disinfected. Area fumigation typically is allowed an overnight retention time to ensure the effectiveness of the procedure. Following fumigation, the formaldehyde is neutralized with ammonia gas by heating ammonium bicarbonate and the area is opened, ventilated, and cleaned. Exact amounts of paraformaldehyde and ammonium bicarbonate used are calculated based on the area to be treated to assure complete disinfection and neutralization. Only people involved with the operation are allowed in the building during fumigation.

2.3.11 Waste Stream Management. Current commercial activities at Greer Laboratories generate various waste streams. The following chart summarizes the type, average amount, and disposal method of waste streams currently generated at Greer Laboratories. It also includes the estimated amount of each waste stream expected to be generated by JVAP activities. Although solid and liquid infectious wastes are not currently generated, these waste have been generated and safely disposed when past BSL3 activities were conducted at the laboratory.

WASTE STREAM TYPE	CURRENT ANNUAL TOTAL GENERATED	JVAP TOTAL PER YEAR (estimated)	DISPOSAL CONTRACTOR
General solid waste	100 cubic yards	5 cubic yards	GDS, Inc, Lenoir, NC
Hazardous chemical waste	660 gallons	none	M&M Chemical Attalla, AL
Wastewater (sterilized with sodium hypochlorite prior to disposal)	150,000 gallons	5,000 gallons	Dept of Sanitation, Lenoir (via municipal sewer)
Animal waste	500 pounds	none	GDS, Inc, Lenoir, NC
Sharps	500 pounds	25 pounds	GDS, Inc, Lenoir, NC
Liquid infectious (autoclaved prior to disposal)	none	500 gallons	Dept of Sanitation, Lenoir (via municipal sewer)
Solid infectious (autoclaved prior to disposal)	none	100 pounds	GDS, Inc, Lenoir, NC
Radiological waste	none	none	None

Wastes from the JVAP-sponsored work will be disposed in accordance with existing procedures. All infectious laboratory waste will be autoclaved prior to being removed from the BSL-3 laboratory. Autoclaving effectively kills all infectious or potentially infectious materials. After autoclaving, solid waste will be disposed via a municipal waste contractor. All aqueous liquid waste from drains will be collected in a 1000-gallon tank which contains a small amount (approximately 5 gallons) of sodium hypochlorite. A 1% solution of sodium hypochlorite is an effective disinfectant for many bacterial and viral organisms. Additional sodium hypochlorite is added as the tank is filled. When the level in the tank reaches 515 gallons, discharges to the tank are stopped, additional sodium hypochlorite is added, and the to assure the contents of the tank are thoroughly decontaminated by a timed (12-hour) decontamination cycle prior to discharge to the sanitary sewer. The tank has two high level alarms to indicate when discharges to the tank are stopped and the decon cycle is started. No hazardous chemical waste is expected to be generated.

3.0 Alternatives Considered

3.1 Alternative I - Perform JVAP activities including production of vaccine at another location. Few facilities exist and are available that have the expertise and appropriate equipment to produce this attenuated virus vaccine for the JVAP. Large scale biomedical product manufacturers are generally not willing to take on a small scale project such as this because it is not economically feasible unless there is a larger market for the product. Most small scale labs that may be willing to take on the project do not have the stringent BSL3 manufacturing capability.

Greer Laboratories was identified as the only site that possessed the appropriate manufacturing capability for this small scale BSL 3 project.

3.2 Alternative II - Alternate vaccines. There are various methods for producing vaccines. A formalin-killed version of the equine encephalitis vaccine was considered, however, it does not produce a good immune response. The currently available equine encephalitis vaccine, a live attenuated vaccine derived from older methods, is not licensed and causes a 25% illness rate. These options were considered not acceptable by JVAP to meet FDA requirements for a safe, effective, licensed product.

3.3 Alternative III - Do not perform JVAP activities including vaccine production. Choosing not to execute JVAP activities will fail to meet the JVAP mission requirements. For example, not producing the equine encephalitis vaccine will result in a failure to assure that an adequate supply is available to protect U.S. military personnel who may be exposed to the agent that causes the disease. Note that military vaccines against equine encephalitis have been used in the past to protect livestock and wildlife (whooping cranes) from indigenous disease in the United States.

4.0 Affected Environment

4.1 Location and Physical Description. Greer Laboratories, Inc is located in Lenoir, NC, Caldwell County, in northwestern North Carolina.

4.2 Land Use. The Lenoir area is largely light industrial; primarily furniture manufacturing. 58% of those employed in Caldewell County are employed in furniture manufacturing.

4.3 Climate. The climate in Lenoir, NC is temperate with average rainfall. Average daytime high temperatures range from a high in the mid 80's in July to a low in the mid 40's in January. Average daytime low temperatures range from 60's to 20's. Monthly average precipitation varies from a low of approximately 3 inches in January to a high of over 4 inches.

4.4 Geology. Lenoir, NC is located in the foothills of the Blue Ridge Mountains, at the edge of the Piedmont Belt. This area is characterized by gently rolling, well-rounded hills and long low ridges.

4.5 Water Resources. Water for the City of Lenoir comes from the Catawba River. The maximum daily capacity for the city is 12 million gallons per day. The Catawba River flows 225 miles from the Blue Ridge Mountains in NC to Lake Wateree east of Columbia SC. The river flows through 14 counties with a total population of over 1.5 million people.

4.6 Plant and Animal Ecology. The Lenoir area has a variety of plants and animals typical to the temperate, east coast climate. The US Fish & Wildlife Service lists several endangered species for Caldwell County including 4 bird species, 2 invertebrate species, and 6 plant species.

4.7 Air Quality. Greer Laboratory is located in the Asheville Air Quality Index Region of North Carolina. The region's air quality is currently in attainment with all the National Ambient Air Quality Standards. The attainment status of the operational area precludes the need for a Clean Air Act General Conformity Review.

4.8 Socioeconomic Environment. The 1998 population of Lenoir was 15,890. The 1998 employment rate in Caldwell County was 97.6% with 42.7% employed in manufacturing. The median family income was $44,500.

5.0 Environmental Consequences.

5.1 Introduction. JVAP-sponsored activities at Greer including production of equine encephalitis vaccine are not expected to result in significant adverse impact to the environment. Proposed activities are not expected to result in the release of any potentially infectious materials to the environment due to the design of the facilities and elaborate safety procedures in place for handling the materials. The potential for direct or indirect effects of the proposed action are discussed below.

5.2 Environmental Consequences of the Proposed Action.

5.2.1 Land Use, Geology, and Soils. Since proposed JVAP-sponsored activities will be confined to inside existing facilities, no adverse effects on land use, geology, or soils are expected.

5.2.2 Effects on Air Quality. Emissions from the Class IIB2 BSCs to be located in the BSL3 Greer facility pass through a High Efficiency Particulate Air Filter (HEPA) prior to being exhausted to the ambient air. The HEPA filter is 99.7% efficient for particles 0.3 microns in size, and will significantly reduce the risk of accidental release of biological materials from the laboratory to the ambient air.

When fumigation of the working area, biosafety cabinets, and filters is performed using paraformaldehyde, vents and ducts to the external ambient air and to other portions within the facility will be sealed off. Following the appropriate exposure period, the formaldehyde gas will be chemically neutralized by the addition of ammonia gas produced by heating ammonium carbonate. The reaction between formaldehyde gas and ammonia gas produces water and a solid material, hexamethylenetetramine, which is deposited on surfaces as a fine powder. The hexamethylenetetramine is vacuumed or wiped from the surfaces and is disposed appropriately. The heating of ammonium carbonate produces a small amount of carbon dioxide which is harmless to the environment.

Emissions to the ambient air from the BSL3 laboratory processes during the equine encephalitis vaccine will not have an impact on the air quality. Emissions from operations using the biological materials are filtered via a HEPA to eliminate particulate emission to the ambient air.

5.2.3 Effects on Odor and Noise. No unusual odor factors are expected to be released outside of the building in support of the JVAP-sponsored activities. Paraformaldehyde used in fumigating the biological suite has a pungent odor but the odor is not released outside the building because the area is sealed when being fumigated and the formaldehyde gas is neutralized before the area is ventilated.

Some minor increase in noise is expected from construction equipment during laboratory modifications, but these will be limited and of short duration, so no lasting impact is anticipated.

Noise during vaccine production will not differ from current operations.

5.2.4 Effects on Water Quality. No significant effects on water quality are expected due to building modification or performing the proposed JVAP activities including equine encephalitis vaccine production. All potentially infectious liquids from proposed laboratory activities will be autoclaved prior to discharge to a holding tank where they will be further treated with sodium hypochlorite. Shower water and other laboratory wastewater will also be treated in the tank prior to discharge. After sterilization/decontamination, the non-hazardous liquid wastes will be discharged to the sanitary sewer. The holding tank is inspected annually to assure no leakage to ground water.

5.2.5 Effects on Solid Waste Disposal. No significant effects are expected from solid wastes generated during building modification or production of the vaccine. All non-hazardous, municipal-type solid waste is disposed of by an existing municipal waste contractor. Potentially infectious solid waste resulting from the vaccine production processes will be autoclaved prior to disposal, thus rendering it harmless. The liquid autoclaved wastes will then be separated from all remaining wastes. Liquid waste from the vaccine production will be further chemically treated with sodium hypochlorite prior to discharge to the sanitary sewer. Because potentially infectious materials are destroyed prior to discharge, disposal of waste resulting from the JVAP-sponsored vaccine production activities will have no adverse impact on human health or the environment.

5.2.6 Effects on Human Health and Safety. No significant effects on human health and safety are expected during building modifications or production of the vaccine. The negative-pressure air-handling system includes HEPA filtration of air discharges to prevent release of potentially infectious agents to the environment outside the BSL3 areas. The safety equipment, safety procedures, and security features incorporated into the design and operation of the facility also prevent accidental releases of hazardous materials to the environment. Workers will change out of lab clothing and shower out before leaving the BSL3 laboratory, which will prevent transfer of potentially infectious materials out of the facility. Workers inside the BSL3 laboratory are protected from exposure to potentially infectious materials by a combination of adherence to strict safety procedures and approved SOPs, handling of materials in biosafety cabinets, and use of personal protective equipment. If vaccines for relevant diseases are available, they will be made available to the workers in the lab.

5.2.7 Effects on Terrestrial and Aquatic Ecosystems. No significant effects are expected on terrestrial and aquatic ecosystems from building modification or production of the vaccine. Since all building modifications will take place inside the existing facility, no habitat disturbance or loss is expected. During operation of the proposed activities, ecosystems are protected by the same safety, security, and facility design requirements that protect air quality and human health and safety. The combination of these procedures, equipment, and facility design will prevent air, water, or solid waste releases of potentially infectious materials to the environment.

5.2.8 Effects on Utilities Including Energy Resources. No significant effects are expected on utilities or energy resources from building modification or production of the vaccine. Water used at Greer Laboratories is provided by the City of Lenoir. Electricity is provided by Duke Power. The JVAP-sponsored work is expected to comprise less than 5% of the water and electricity consumption for the entire facility.

5.2.9 Effects on Socioeconomic Environment and Aesthetics. JVAP-sponsored activities including vaccine production are not expected to have any significant effect on the local economy, public services, revenue generation, social structure, or behavioral patterns in the area. Currently, one professional staff member and three technical employees are designated for JVAP manufacturing activities. If needed, additional personnel may be drawn from other sections within Greer Laboratories to work on the JVAP project. This does change the total number of employees at Greer Laboratories. Since Greer Laboratories routinely handles hazardous materials and BSL-3 work has been done at the facility in the past, the public's perception of safety at the lab is not expected to change substantially. Therefore, the proposed activity is not expected to affect current property values for neighboring land.

5.2.10 Land Use Conflicts. Since proposed JVAP-sponsored activities will be confined to inside existing facilities, no land use conflicts are anticipated.

5.2.11 Unavoidable Adverse Environmental Effects. No unavoidable adverse environmental impacts have been identified.

5.2.12 Environmental Justice. The proposed action is not expected to disproportionately impact minority or low-income populations. The Caldwell County area is not considered a poverty area given that it has less than 20% of the population, including children ages 5-17, in poverty.[3] The median family income is $44,500, well above the national average.

5.2.13 Cumulative Impact. It is highly unlikely that the proposed JVAP-sponsored activities will result in any cumulative impact to the environment because the contributions of the proposed activities to environmental pollution are negligible. The proposed activities will be conducted in existing facilities where all emissions and wastes are controlled.

5.3 Comparison of the Proposed Action with the Alternatives.

5.3.1 Alternative 1 - Produce vaccine at another location. Although no suitable alternative locations were found, the potential impacts associated with performing the work at another location would be comparable to the proposed action. Any facility where the JVAP-sponsored work would be conducted would have to meet Centers for Disease Control/National Institutes of Health (CDC/NIH) requirements for biocontainment and safety procedures. Proper engineering controls and waste disposal practices would be necessary to assure no significant impact to air, water, and land resources.

5.3.2 Alternative 2 - Other vaccines including alternatives for equine encephalitis vaccine. Work with other potential equine encephalitis vaccines would likewise be done in accordance with CDC/NIH requirements for bio containment and safety procedures. Therefore, potential impacts would be comparable to the proposed action.

5.3.3 Alternative 3 - No action. Not executing JVAP activities would result in a failure to meet important mission requirements. Potential adverse environmental impacts associated with the no action alternative are not significantly less than executing the proposed action since existing facilities are proposed to be used.

6.0 Conclusions.

This EA has examined the potential for environmental impacts resulting from proposed JVAP-sponsored activities at Greer Laboratories, Inc. This includes the production of an attenuated recombinant equine encephalitis vaccine in building #6 at Greer Laboratories. The Preferred Alternative (Proposed Action) includes minor renovation of existing facilities at Greer Laboratories to accommodate the proposed JVAP activities. Potential direct environmental effects evaluated in the EA include air quality, noise, odor, water quality, solid waste disposal, human health and safety, and utilities. Potential indirect effects evaluated include socioeconomic effects, impact due to facility renovations, and aesthetics. Additional analyses required by NEPA that were addressed include determination of land use conflicts, unavoidable adverse environmental effects, and cumulative impact.

Procedural, engineering, and managerial safeguards ensure the mitigation of effects associated with normal operation. These safeguards include: safety management, staff safety training, SOPs, protective clothing, biological safety cabinets, air filtration equipment, decontamination, and site security.

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[3] U.S. Census Bureau, Population as of Jul 96

This EA concludes with a finding that no significant adverse impact on human health or the environment is anticipated from proposed action. Potential impacts of the various operations on the laboratory workers would be minimized by a combination of adherence to strict safety procedures and approved SOPs, handling of biological materials in biosafety cabinets, and use of personal protective equipment. No effects on cultural or historic resources and no land use conflicts are expected, since an existing building will be used. A finding of no significant impact (FNSI) will be published in the North Carolina Environmental Bulletin by the North Carolina State Clearinghouse.

7.0 Persons and Agencies Contacted

Greer Laboratories, Inc.
Dr. Ronald J. Arndt, Director of Vaccine Production
Mr. Ed Cannon, Director of Engineering and Facilities
Ms. Brenda Roper, Environmental Health & Safety Officer

DynPort
Dr. Venkat Rao, Director, Environment and Health

Edgewood Chemical Biological Center
Ms. Elizabeth Hirsh, Environmental Scientist
Mr. Greg Mason, Safety Specialist

North Carolina State Clearinghouse
Ms. Chrys Baggett

8.0 Acronyms

BMBL	Biosafety in Microbiological and Biomedical Laboratories
BSL	Biosafety Level
DoD	Department of Defense
FDA	Food and Drug Administration
GMP	Good Manufacturing Practices
HEPA	High Efficiency Particulate Air
JPO BD	Joint Program Office for Biological Defense
JVAP	Joint Vaccine Acquisition Program